SEP 2 3 2004

K042105 **APPENDIX E**

Summary of Safety and Effectiveness

General Provisions:

Trade Name: Clipper Diagnostic Electrode Catheter

Common/Classification Name: Electrode recording catheter.

Name of Predicate Devices:

Bard Viking Diagnostic Electrode Catheter

Bard Woven Diagnostic Electrode Catheter

Classification:

Class II

Performance Standards:

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Intended Use and Device Description:

Bard Electrophysiology's fixed diagnostic electrode catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

The device description of the Clipper Diagnostic Electrode catheter is as follows:

- 6F
- woven fixed curve construction
- 113 – 128cm usable length
- Curve Configurations: Josephson, Cournand, & Damato
- Electrode Spacing: 2mm / 5mm / 2mm, 5mm / 1cm
- Number of Electrodes: 4
- Electrode Width: 1.5mm Proximal / 2mm Distal
- Cable: EasyMate

Biocompatibility:

All tissue and body fluid contacting materials used in the Clipper catheter are biocompatible.

Summary of Substantial Equivalence:

The Clipper Diagnostic Electrode Catheters are substantially equivalent to the previously cleared Viking Diagnostic Electrode catheters and to the Pre-Amendment Woven Diagnostic Electrode catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2004

Bard Electrophysiology
c/o Ms. Deborah L. Herrington
Manager, Regulatory Affairs
55 Technology Drive
Lowell, MA 01851

Re: K042105
Trade Name: Clipper Diagnostic Electrode Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: II (two)
Product Code: DRF
Dated: September 03, 2004
Received: September 07, 2004

Dear Ms. Herrington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K042105

Device Name: Clipper Diagnostic Electrode Catheter

Indications For Use: Bard Electrophysiology's fixed diagnostic electrode catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

Contraindications: The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042105